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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,159	02/05/2002	Bernard Bihain	29.US4.DIV	2627

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LLOYD & SALIWANCHIK
2421 N. W. 41 ST. STREET
SUITE A-1
GAINESVILLE, FL 32606-6669

EXAMINER	
HUNNICUTT, RACHEL KAPUST	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,159	BIHAIN ET AL.	
	Examiner	Art Unit	
	Rachel K. Hunnicutt	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *72-85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 1-14 have been renumbered claims 72-85.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 72 and 74-77, drawn to methods of using an agent as a medicament, classified in class 514, subclass 2.

II. Claim 73, drawn to a peptide comprising the consensus sequence of SEQ ID NO: 1, classified in class 500, subclass 300.

III. Claim 73, drawn to a peptide comprising the consensus sequence of SEQ ID NO: 2, classified in class 500, subclass 300.

IV. Claims 78-80, drawn to methods of identifying candidate pharmaceutical agents by identifying a compound comprising SEQ ID NO: 1 and administering the compound, classified in class 424, subclass 9.2

V. Claims 78-80, drawn to methods of identifying candidate pharmaceutical agents by identifying a compound comprising SEQ ID NO: 2 and administering the compound, classified in class 424, subclass 9.2.

VI. Claims 81-84, drawn to methods of using an agent to decrease the activity of a compound which increases the partitioning of dietary lipids, classified in class 424, subclass 94.6.

VII. Claim 85, drawn to a method for determining whether an obese individual is at risk of suffering from a condition by determining if the individual has a lower than normal level of adipoQ activity, Apm1 activity or activity of a compound analogous thereto, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Group I and Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptides of Groups II and III can be used in a variety of methods such as purification assays, ligand binding assays or other diagnostic assays. Group I is distinct from Groups IV, V, and VIII because the methods are drawn to different conditions and thus have different goals and different outcome measures. Group I is not related to Group VI. The methods require different reagents and different method steps, and have different goals and different outcome measures.

Groups II and III are not related. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are structurally and functionally distinct and cannot be used together or interchangeably. Group I is drawn to a peptide comprising by SEQ ID NO: 1 and Group III is drawn to a peptide comprising SEQ ID NO: 2. They differ structurally and functionally and cannot be used together or interchangeably. Group II is related to Groups IV and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptides of Group II can be used in a variety of methods such as purification assays, ligand binding assays or other diagnostic assays. Group II is not related to Groups V and VI. The peptide of Group II cannot be used in the methods of Groups V and VI.

Group III is related to Groups V and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide of Group III can be used in a variety of methods such as purification assays, ligand binding assays or other diagnostic assays. Group III is not related to Groups IV and VI. The peptide of Group III cannot be used in the methods of Groups IV and VI.

Group IV is distinct from Groups V and VII because the methods are drawn to different conditions and thus have different goals and different outcome measures. Group IV is not related to Group VI. The methods require different reagents and different method steps, and have different goals and different outcome measures.

Group V is distinct from Group VIII because the methods are drawn to different conditions and thus have different goals and different outcome measures. Group V is not related to Group VI. The methods require different reagents and different method steps, and have different goals and different outcome measures.

Group VI is not related to group VII. The methods require different reagents and different method steps, and have different goals and different outcome measures.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I

a) methods of treatment: treating a condition by increasing the partitioning of dietary lipids to the liver, treating a condition by reducing the levels of free fatty acids in obese individuals, decreasing the body weight of obese individuals

b) obesity related conditions: atherosclerosis, insulin resistance, hypertension, and type II diabetes

c) agents: C1q, AdipoQ, ApM1, Acrp 30, cerebellin, and multimerin

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If Applicant elects Group I, Applicant must elect one species from a), b), and c) for prosecution.

Group VI

a) agents: agent that decreases activity of AdipoQ, agent that decreases activity of ACRP30, and agent that decreases activity of ApM1

If Applicant elects Group VI, Applicant must elect one species from a).

Group VII

a)conditions: condition associated with a lower than desirable level of partitioning of dietary lipids to the liver, atherosclerosis, insulin resistance, hypertension, Type II diabetes

If Applicant elects Group VII, Applicant must elect one species from a).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct and/or unrelated for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the searches required for the different groups are different from each other, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
9/14/04

SHARON L. TURNER, PH.D.
PATENT EXAMINER

9-14-04